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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/724,301 | 11/26/2003 | Barbara Enenkel | 1/1411 | 5533 |
| 28501 | 7590 | 01/11/2006 | EXAMINER | |
| MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368 | | | WALICKA, MALGORZATA A | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1652 | | |
| DATE MAILED: 01/11/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/724,301 | ENENKEL ET AL. |
| | Examiner | Art Unit |
| | Malgorzata A. Walicka | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-5, 9, 11, 16 in part, and 24, drawn to a neomycin phosphotransferase mutated in positions 91, 198 and /or 240, its encoding gene, expression vector, host cell, and a method of use of the vector for enriching of mammalian cell, classified in class 436, subclass 325.
- II. Claim 6-8, 10, 12, 14-15, 16 in part, 17-18, 25-26, 30-31 and 33, drawn to a eukaryotic expression vector containing a gene encoding neomycin phosphotransferase mutated in positions 182, 227, 261, its encoding gene, expression vector, host cell, and a method of use of the vector for enriching of mammalian cell, classified in class 435, subclass 325.
- III. Claim 13, 19-23, 27, 28 and 29 drawn to eukaryotic expression vector containing a neomycin phosphotransferase gene, wherein said phosphotransferase has a lower activity compared with wild-type neomycin phosphotransferase, and a host cell, classified in class 435, subclass 320.1.
- IV. Claim 34, 36, 40, 44-45, 47-50 drawn to a method of obtaining and selecting a mammalian cell which expresses at least one heterologous gene of interest and the gene of claim 1, as well as to a method of

producing at least one protein of interest, classified in class 435, subclass 69.1.

V. Claim 35, 37, 41, 46 and 51-54 drawn to a method of obtaining and selecting a mammalian cell which expresses at least one gene of heterologous gene of interest and the gene of claim 6, as well as to a method of producing at least one protein of interest, classified in class 435, subclass 69.1.

VI. Claim 38-39 and 42-43, drawn to a method of obtaining and selecting a mammalian cell which expresses at least one gene of heterologous gene of interest and the gene encoding a phosphotransferase having lower activity, classified in class 435, subclass 69.1.

Invention I-VI are distinct for the following reasons.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products and one method of use of said products.

Invention I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different chemical products.

Invention I and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a product and a producton of other products. The inventions are not disclosed as capable of use together.

Invention II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different chemical products.

Invention II and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a product and producton of other products. The inventions are not disclosed as capable of use together.

Invention III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a product and producton of other products. The inventions are not disclosed as capable of use together.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, as well as the search required for Group I-VI is overlapping but not coextensive, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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INTERLOCUTORY PATENT EXAMINER
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